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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Edouard G. Lebel

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06/26/2007

SYNGENTA BIOTECHNOLOGY, INC.

PATENT DEPARTMENT

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

06/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/901,737	LEBEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007 and 14 May 2007.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 51-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-54, 56-65 is/are rejected.
- 7) ☐ Claim(s) 55 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 January 2007 has been entered.
2. Claims 51-65 are pending.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Objections***

4. Claims 63 and 65 are objected to because "mitochondria" is misspelled.

### ***Claim Rejections - 35 USC § 112***

5. Claims 51, 53, 57, 61 and 63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 17 July 2006, as applied to claims 8-9, 14, 20-23 and 30-34. Applicant's arguments filed 16 January 2007 have been fully considered but they are not persuasive.

Claims 53 and 61 require that the microbial  $\beta$ -1,4-endoglucanases be thermostable. The specification fails to describe the structural features that confer thermostability on a microbial  $\beta$ -1,4-endoglucanase.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, the disclosed species are insufficient to describe the claimed genus.

Hence, Applicant has not, in fact, described plants transformed with nucleic acids that encode thermostable microbial  $\beta$ -1,4-endoglucanases within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

Applicant urges that Jung, Gilkes and Henrissat teach the structural elements of numerous microbial endoglucanases (response pg 6-7)

This is not found persuasive. While Gilkes and Henrissat have overcome a portion of the rejection (the lack of description of any microbial endoglucanase other than *T. fusca* E1, E2 or E5), neither describe the structural features that confer thermostability on a microbial  $\beta$ -1,4-endoglucanase. The structural features that distinguish thermostable microbial  $\beta$ -1,4-endoglucanases from nonthermostable microbial  $\beta$ -1,4-endoglucanases is not described.

6. Claims 51, 53 and 57-65 are rejected under 35 U.S.C. 112, first paragraph, because the

specification, while being enabling for plants transformed with *T. fusca*  $\beta$ -1,4-endoglucanase-encoding sequences, does not reasonably provide enablement for plants transformed with nucleic acids encoding any microbial  $\beta$ -1,4-endoglucanase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is modified from the rejection set forth in the Office action mailed 17 July 2006, as applied to claims 8-9, 14, 20-23 and 30-34. Applicant's arguments filed 16 January 2007 have been fully considered but they are not persuasive.

The claims are broadly drawn to plants transformed with a nucleic acid encoding any thermostable microbial  $\beta$ -1.4-endoglucanase.

In contrast, the instant specification, however, only provides guidance for expression of constructs comprising a nucleic acid encoding the *T. fusca* E1, E2 or E5  $\beta$ -1.4-endoglucanase operably linked to the tobacco PR-1a or the CaMV 35S promoter in tobacco, maize or wheat (example A) and similar expression in plants of constructs encoding fusion proteins of those endoglucanases and a vacuolar signal sequence (example B).

The specification only teaches one source of thermostable microbial  $\beta$ -1,4-endoglucanases, those from *T. fusca*, and does not teach how to make other thermostable microbial  $\beta$ -1,4-endoglucanases.

Additionally, claims 63 and 65 encompass plants transformed in their plastids with constructs comprising targeting sequences that target the microbial  $\beta$ -1,4-endoglucanase to the vacuole, mitochondria, peroxisome, ER, apoplast, or for extracellular secretion. The specification teaches no such targeting sequences that function on a protein that is made within

the chloroplast and that targets the protein out of the chloroplast and into another organelle. This is not a process that occurs in plant cells.

Given the claim breath and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

Applicant urges that Jung, Gilkes and Henrissat teach numerous microbial endoglucanases (response pg 8).

This is not found persuasive. While Gilkes and Henrissat have overcome a portion of the rejection, they do not teach thermostable microbial  $\beta$ -1,4-endoglucanases other than those from *T. fusca*, which are the only thermostable microbial  $\beta$ -1,4-endoglucanases taught in the specification.

Applicant urges that Jung teaches the similarities and differences between thermophilic and nonthermophilic endoglucanases (response pg 9).

This is not found persuasive because Jung teaches no clear distinguishing features of thermostable endoglucanases. *C. thermocellum* celD has features not present in the *T. fusca* enzymes (paragraph spanning pg 3039-3940), although *C. thermocellum* is presumably thermophilic, while sharing sequence with presumably nonthermophilic enzymes. There is no structure identified as identifying an endoglucanase as thermophilic.

### ***Claim Rejections - 35 USC § 103***

7. Claims 51-54, 56-58 and 60-65 rejected under 35 U.S.C. 103(a) as being unpatentable over Van Ooyen et al (US Patent 5,705,375, filed June 1992) in view of Lao et al (1991, J. Bacteriol. 173:3397-3407. The rejection is modified from the rejection set forth in the Office

action mailed 17 July 2006, as applied to claims 8, 14-15 and 21-23. Applicant's arguments filed 16 January 2007 have been fully considered but they are not persuasive.

The claims are drawn to plants transformed with a nucleic acid encoding a microbial endo- $\beta$ -1,4-glucanase operably linked to a plant promoter.

Van Ooyen et al disclose plants and seeds whose nucleus is transformed with the *Bacillus licheniformis*  $\alpha$ -amylase coding sequence under control of a constitutive (35S) promoter or an inducible (patatin) promoter (column 11, lines 45, to column 14, line 57). Van Ooyen et al also disclose use of tissue specific and developmental stage specific promoters (claims 2, 8 and 10; column 6, lines 13-26) and targeting the protein to various cellular compartments, including the chloroplast, mitochondria and vacuole (column 6, line 53, to column 7, line 3; column 3, lines 39-46 and 62-65; claim 4).

Van Ooyen et al do not disclose plants transformed with a nucleic acid encoding microbial endo- $\beta$ -1,4-glucanase.

Lao et al teach nucleic acids encoding the *T. fusca* E2 and E5  $\beta$ -1,4-endoglucanases, which are thermostable.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the plants and seeds taught by Van Ooyen et al, to express microbial endo- $\beta$ -1,4-glucanases in them, including those taught by Lao et al. One of ordinary skill in the art would have been motivated to do so because of the suggestion of Van Ooyen et al to express microbial  $\beta$ -1,4-endoglucanases in plants (column 4, lines 11-36). Tissue specific and developmental stage specific promoters would determine a spatial and temporal expression pattern on the microbial  $\beta$ -1,4-endoglucanase. One of ordinary skill in the art would have been

motivated to use the microbial endo- $\beta$ -1,4-glucanases taught by Lao et al because they were available and selection of one microbial endo- $\beta$ -1,4-glucanase over another is an obvious design choice and optimization of experimental parameters.

Applicant urges that Van Ooyen et al does not provide motivation to express endo- $\beta$ -1,4-glucanase in a temporal or spatial manner (response pg 9-10).

This is not found persuasive because motivation is found in column 3, lines 62-65, which discusses expressing more than one enzyme in a tissue-specific or developmental manner; those additional enzymes are listed in column 4, lines 11-36 and include endo- $\beta$ -1,4-glucanase.

Applicant urges that expression of cellulose degrading enzymes in a cellulose containing organism like a plant is counterintuitive, and Van Ooyen et al does not address the problem or suggest how to overcome it (response pg 10).

This is not found persuasive. Van Ooyen et al teaches targeting the protein to various cellular compartments, including the chloroplast, mitochondria and vacuole (column 6, line 53, to column 7, line 3) and teaches use of tissue-specific or developmental promoters (column 3, lines 62-65; column 6, lines 13-26). Both of these would overcome the problem Applicant discusses.

Applicant urges that endo- $\beta$ -1,4-glucanase is mentioned as part of laundry list; further, although endo- $\beta$ -1,4-glucanase were well-known, no attempt was made in the art to express them in plants (response pg 10).

This is not found persuasive. Van Ooyen et al explicit suggest to express endo- $\beta$ -1,4-glucanase belies Applicant's assertion that there is no motivation to do so.

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8. Claims 55 and 59 are free of the prior art, given the failure of the prior art to teach a plant transformed with a construct comprising a wound- or chemically-inducible promoter operably linked to a nucleic acid encoding a microbial endo- $\beta$ -1,4-glucanase.
9. Claim 55 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Conclusion*

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

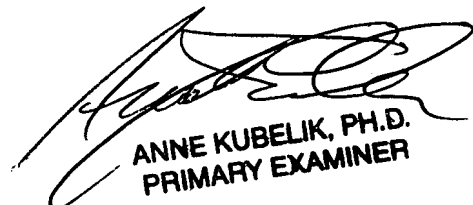
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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Anne Kubelik, Ph.D.  
June 20, 2007



ANNE KUBELIK, PH.D.  
PRIMARY EXAMINER